

different immunization schedule,  
and

(b) comparing the incidence, prevalence or frequency of at least one chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the incidence or severity of said chronic immune mediated disorder(s), and

II. selecting an immunization schedule which protects humans against such infectious disease, but would be expected to result in a reduced incidence, prevalence or frequency of said disorder relative to that observed in at least one of said groups.

264 (new). The method of 263 further comprising comparing the incidence, prevalence, frequency or severity of said infectious disease in the same or equivalent groups.

265 (new). The method of claim 153 in which three or more groups, each with a different immunization schedule, are compared.

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**REMARKS**

In order to better protect the invention, additional claims have been added which, applicant hopes, overcome the issues raised by the Examiner against the pending claims.

Claims 153-247 and 250-255 are to a method which comprises both (I) screening two or more immunization schedules for their effect on the risk of a chronic-immune mediated disorder, (II) immunizing at least in part according to the schedule shown to

be associated with a lower risk. Unlike the present method-of-use claims, they recite a screening step, and hence do not need a complex disclaimer to avoid inherent anticipation by vaccination experiments that did not consider CIMD effects. Unlike the "Kit" claims, they do not rely on printed "instructions for use" or "warnings" to avoid inherent anticipation.

Claims 248-249 relate to protecting a subject against an infectious disease while reducing the risk of said subject thereby developing a CIMD. Like claim 153, they recite both (I) screening and (II) immunizing. Claims 256-259 is similar to 248, but recite a previous determination as to the effect of immunogen timing on CIMD risk. Claims 259-261 are similar to 248 but recite "determining" in place of "screening".

Claims 262-263 are business method claims.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made".

Respectfully submitted,

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